IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF VIRGINIA
Norfolk Division

AVENTIS PHARMA DEUTSCHLAND GMBH and
KING PHARMACEUTICALS, INC.,
Plaintiffs

v. **Civil Action No. 2:05cv421**

LUPIN LTD. and
LUPIN PHARMACEUTICALS, INC.
Defendants.

MEMORANDUM OPINION AND ORDER

This case involves alleged patent infringement on the part of a generic drug company. Plaintiffs Aventis Pharma Deutschland GMBH ("Aventis") and King Pharmaceuticals, Inc. ("King") have brought a two-count suit against Defendants Lupin Ltd. and Lupin Pharmaceuticals, Inc. for patent infringement and inducement of infringement. Two matters are presently before this Court: 1) Plaintiffs' Motion to Stay the Proceedings, and 2) Defendants' Motion to Dismiss. For the reasons stated herein, these motions are **DENIED**.

I. Background

The action leading to this suit is straightforward. Plaintiff Aventis owns U.S. Patent No. 5,061,722, known as the " '722 patent." The '722 patent involves a pharmaceutical compound known as "ramipril" used to treat high blood pressure. Co-plaintiff King Pharmaceuticals is the exclusive licensee of the '722 patent, marketing ramipril under the trade name "ALTACE."

On March 18, 2005, Lupin Ltd., a generic drug company based in India, submitted an

"Abbreviated New Drug Application" ("ANDA") to the Food and Drug Administration (FDA) seeking approval to market generic versions of ramipril capsules. The ANDA application procedure was created by Congress in 1984, under what is commonly known as the "Hatch-Waxman Act." Warner-Lambert Co. v. Apotex Corp., 316 F.3d 1348, 1352 (Fed. Cir. 2003); see 21 U.S.C. § 355(j)(2)(A). The purpose of the ANDA process is to expedite the approval of generic drugs, which are cheaper than "pioneer" drugs, by creating an "exemption or 'safe harbor' for activities that would otherwise constitute patent infringement." SmithKline Beecham Corp. v. Geneva Pharm., Inc., 287 F. Supp. 2d 576, 582 (E.D. Penn. 2002). Section § 271(e)(1) of Title 35 provides:

> It shall not be an act of infringement to make, use, offer to sell, or sell within the United States or import into the United States a patented invention . . . solely for the uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products.

In this way, generic drug companies may develop and submit information to the FDA in order to gain regulatory approval for a generic version of a drug already approved by the FDA prior to the expiration of that drug's patent.

While this "safe harbor" is provided to generic drug companies, provisions protecting the "pioneer" companies are also present under the Act. Immediately following § 271(e)(1), § 271(e)(2) provides that "[i]t shall be an act of infringement to submit":

> (A) an application under section 505(j) of the Federal Food, Drug, and Cosmetic Act or described in section 505(b)(2) of such Act for a drug claimed in a patent or the use of which is claimed in a patent, . . . if the purpose of such submission is to obtain approval under such Act to engage in the commercial manufacture, use, or sale of a drug or veterinary biological product claimed in a patent or the use of which is claimed in a patent before the expiration of such patent.

35 U.S.C. § 271(e)(2). It doesn't take an astute reader to discern that § 271(e)(2) directly contradicts § 271(e)(1). There was, however, a method to Congress' incongruity, apparently, as the United States Supreme Court concluded that the purpose of § 271(e)(2) was to create a "highly artificial" act of infringement to allow for subject matter jurisdiction in a district court to resolve any disputes about infringement *before* the generic drug is sold.[1] Eli Lily and Co. v. Medtronic, Inc., 496 U.S. 661, 679 (1990). Accordingly, filing an ANDA application is not a willful act of infringement in and of itself. Glaxo Group Ltd. v. Apotex, Inc., 376 F.3d 1339, 1351. Rather, "[t]his highly artificial act of infringement gives rise to only a limited set of statutorily-defined consequences set forth in 35 U.S.C. § 271(e)(4)" if actual infringement is shown.[2] Id. Thus, "[i]f a manufacturer

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[1]Although this is an act of infringement, it was not designed to prevent generic drug manufacturers from filing; rather, "section 271(e)(2) employs the legal fiction of a defined act of infringement to create case or controversy jurisdiction, thereby enabling a court to promptly resolve any dispute concerning infringement and validity of the subject patent." Zeneca Ltd. v. Mylan Pharm., Inc., 173 F.3d 829, 836 (Fed. Cir. 1999)(Rader, J. concurring). In fact, the Act provides generic companies with an incentive to file Paragraph IV certifications, as "the first generic manufacturer to file an ANDA containing a Paragraph IV certification for a specific drug receives a 180-day exclusivity period to market its version of the generic drug without competition from other ANDA applicants." In re K-Dur Antitrust Litigation, 338 F.Supp.2d 517, 524 (D.N.J. 2004).

[2]Under 35 U.S.C. § 271(e)(4), the remedies available to the pioneer company in these cases are:

> (A) the court shall order the effective date of any approval of the drug or veterinary biological product involved in the infringement to be a date which is not earlier than the date of the expiration of the patent which has been infringed,
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> (B) injunctive relief may be granted against an infringer to prevent the commercial manufacture, use, offer to sell, or sale within the United States or importation into the United States of an approved drug or veterinary biological product, and
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> (C) damages or other monetary relief may be awarded against an infringer only if there has been commercial manufacture, use, offer to sell, or sale within the United States or importation into the United

goes beyond mere preparation," these remedies are available. Upjohn Co. v. Mova Pharm. Corp., 899 F.Supp. 46, 49 (D.P.R. 1995).

When a company files an ANDA, it must follow the content requirements established in 21 U.S.C. § 355(b). As part of these requirements, ANDA applicants must make one of four certifications related to the status of the "pioneer" patent. Id. In this case, Lupin Ltd. certified that Plaintiffs' patent "is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted" under paragraph IV of the provision. See § 355(b)(2)(A)(iv). This is commonly known as "paragraph IV certification." Warner-Lambert, 316 F. 3d at 1352.

ANDA applicants with paragraph IV certification must also send a notification letter to the holder of that patent and to the holder of the original New Drug Application approved by the FDA. 21 U.S.C. § 355(j)(2)(B). After being notified, pioneer drug makers are then able to bring "a legal action for patent infringement before the generic drug maker has begun marketing." Geneva, 287 F. Supp. 2d at 582 (quoting H.R. Rep. 98-857(I), 1984 U.S.C.C.A.N. 2647); see 35 U.S.C. § 271(e)(2)(A). In order to bring a legal action under these circumstances, however, the original patent owner must act quickly upon receipt of notification, filing suit within 45 days or the ANDA application will be approved. 21 U.S.C. § 355(c)(3)(C). If the original patent owner brings suit, "then [FDA] approval may not be made effective until the court rules that the patent is not infringed

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States of an approved drug or veterinary biological product.

> The remedies prescribed by subparagraphs (A), (B), and (C) are the only remedies which may be granted by a court for an act of infringement described in paragraph (2), except that a court may award attorney fees under section 285.

35 U.S.C. § 271(e)(4).

or until the expiration of (in general) 30 months, which ever first occurs." Eli Lily, 496 U.S.C. at 677-78. Obviously, this process is designed to allow for the court to resolve any claim of infringement the original patent owner may have against the ANDA applicant as quickly as possible, and, indeed, the statute requires that, in these actions, "each of the parties shall reasonably cooperate in expediting the action." 21 U.S.C. § 355(c)(3)(C).

In this case, Lupin Ltd. filed its ANDA application for ramipril capsules with the FDA on or about March 18, 2005. Pursuant to 21 C.F.R. § 314.50(a)(5), Lupin Pharmaceuticals, a United States company and subsidiary of Lupin Ltd., an India company, acted as Lupin Ltd.'s agent for the ANDA filing. That regulation requires ANDA applications by foreign drug manufacturers to "contain the name and address of, and be countersigned by, an attorney, agent, or other authorized official who resides or maintains a place of business within the United States."[3] Plaintiffs then received the required notification letter from Lupin Ltd. on June 8, 2005. Pl.'s Am. Compl. ¶ 15 (Document No. 4). In this letter, Lupin Ltd. stated that its ANDA application contained a "paragraph IV certification" and that, in its opinion, "the '722 patent is invalid, unenforceable or will not be infringed by the commercial manufacture, use or sale of Lupin's Ramipril capsules." Id. ¶ 17. The letter also stated that Lupin Ltd. consented to jurisdiction in the United States District Court for the Eastern District of Virginia "[s]olely for the purposes of any infringement action based on

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[3]21 CFR § 314.50(a)(5) provides in its entirety:

> The applicant, or the applicant's attorney, agent, or other authorized official shall sign the application. If the person signing the application does not reside or have a place of business within the United States, the application is required to contain the name and address of, and be countersigned by, an attorney, agent, or other authorized official who resides or maintains a place of business within the United States.

[its ANDA application]." Pl.'s Mot. to Stay Proceedings at Ex. 2 (Document No. 15). Pursuant to 21 C.F.R. § 314.52(7), which outlines the contents of the notification letter, the letter then listed the name and address of its agent in the United States authorized to accept service of process for Lupin.[4] The agent is located in Norfolk, Virginia, which is in the United States District Court for the Eastern District of Virginia.

On July 15, 2005, Plaintiffs filed a patent infringement action against Defendants in the District of Maryland, where Defendant Lupin Pharmaceuticals, has its principal place of business. On July 19, 2005, Plaintiffs filed this suit in the Eastern District of Virginia. This suit is identical to Plaintiffs' Maryland suit. Plaintiffs maintain this subsequent suit "was filed only as a protective measure." Pl.'s Mot. to Stay at 4 (Document No. 16).[5]

On August 29, 2005, Plaintiffs then filed an Amended Complaint. On September 7, 2005, Defendants Answered and filed two counterclaims. Defendant Lupin Pharmaceuticals filed a Motion to Dismiss under Rule 12(b)(6) on the same day. On September 8, 2005, in the District of Maryland, Defendant Lupin Ltd. also moved to dismiss the action for lack of personal jurisdiction under Rule 12(b)(2). According to the parties, as of November 28, 2005, this Motion is still pending. Additionally, Defendant Lupin Pharmaceuticals filed an identical motion to dismiss in that court that it filed in this case.

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[4]21 C.F.R. § 314.52(7) provides:

> If the applicant does not reside or have a place of business in the United States, the name and address of an agent in the United States authorized to accept service of process for the applicant.

[5]Plaintiffs do acknowledge, however, the complaint is subject to the 120-day period for service under Fed. R. Civ. P. 4(m).

On September 20, 2005, Plaintiffs filed an Unopposed Motion for Extension of Time. On September 23, 2005, this Court entered the parties' Agreed Order extending the Motion to Dismiss filing deadline. On October 12, 2005, Plaintiffs filed a Motion to Temporarily Stay Proceedings. On October 25, 2005, this Court entered another Agreed Order extending the deadlines with relation to this Motion. On November 28, 2005, the Court held a hearing on Plaintiffs' Motion to Temporarily Stay Proceedings and Defendants' Motion to Dismiss. It will now address these Motions in turn.

II. Plaintiffs' Motion to Stay Proceedings

A. Standard of Review

A Motion to Stay Proceedings is not expressly provided for by the Federal Rules or by statute, although a district court has the inherent discretion to recognize such a motion under its general equity powers. Williford v. Armstrong World Indus., Inc., 715 F.2d 124, 127 (4th Cir. 1983). While recognizing this power, the United States Court of Appeals for the Fourth Circuit has observed that "it is not, however, without limitation." Id. "[P]roper use of this authority," the Court of Appeals explained, "calls for the exercise of judgment which must weigh competing interests and maintain an even balance." Id. (quoting Landis v. North American Co., 299 U.S. 248, 254-55, 57 S.Ct. 163, 166 (1936)). A party seeking a stay "must justify it by clear and convincing circumstances," and these circumstances must weigh more heavily than the potential harm to the party against whom the stay applies. Id. Accordingly, the applicant for a stay "must make out a clear case of hardship or inequity in being required to go forward . . . ." Id. Otherwise, a stay is not merited. While the standard of review for stays is high, the statutory scheme governing ANDA

applicants makes it higher, as the statute commands that "each of the parties shall reasonably cooperate in expediting the action." 21 U.S.C. § 355(c)(3)(C).

B. Analysis

1. The "First-Filed" Rule

Plaintiffs primarily rely on the "first to file" rule to justify their request for a stay, specifically maintaining they only filed this Virginia suit two business days after filing in Maryland as a "protective measure." Ordinarily, when there is more than one action involving the same patent, the suit filed first proceeds while the second action is stayed. See SCHWARTZ, HERBERT, PATENT LAW AND PRACTICE, §3.V.A. (4th. Ed. 2003)[hereinafter "Patent Law and Practice"]. See Int'l Nickel Co., Inc. v. Barry, 204 F.2d 583, 585 (4th Cir. 1953). This is the "first to file rule," which "giv[es] priority to the first suit absent showing of a balance of convenience in favor of the second." The Learning Network, Inc. v. Discovery Comm., Inc., 11 Fed. Appx. 297, 300 (4th Cir. 2001) (unpublished). While this is generally so, however, the first to file rule applies in contexts not present in this case: 1) either one patent is involved but there are multiple defendants in different forums, see Patent Law and Practice at §3V.A., or 2) the defendant files its own "mirror-image" infringement action in another forum in response to being sued, see First Nationwide Mortgage Corp., et al. v. FISI Madison, LLC, 219 F. Supp. 2d 669, 672 (D. Md. 2002). Here, in contrast, Plaintiffs filed the same case against the same Defendants in two different courts. Generally, "plaintiffs may not file duplicative complaints in order to expand their legal rights." Curtis v. Citibank, N.A., 226 F.3d 133, 140 (2nd Cir. 2000); see also Samsung Elec. Co., Ltd. v. Rambus, Inc., 386 F. Supp. 2d 708, 725 (E.D. Va. 2005) (stating that the first-to-file rule is not to be applied "mechanically" but should consider "equitable concerns and the goal of judicial economy" and

declining to apply it where the party "desperately wanted to avoid litigation in the forum").

There is little question Plaintiffs had two legitimate options for filing suit in either Maryland or Virginia court in this case, as Defendant Lupin Pharmaceuticals has its principal place of business in Maryland but is incorporated in Virginia. See JOHN C. O'QUINN, There's No Place Like Home: Finding Personal Jurisdiction in ANDA Patent Cases After Zeneca v. Mylan Pharmaceuticals, 13 HARD. J.L. & TECH. 129, 143 (1999) (noting a patent holder "could potentially have an arbitrary choice between two forum states in which to file suit against an ANDA infringer – that of its incorporation and that of its principal place of business"). Plaintiffs filed in both jurisdictions, however, blaming Defendants for their decision to file two identical suits. In Plaintiffs's view, Defendants' "Notification Letter," which consented to jurisdiction in the Eastern District of Virginia and designated a Virginia lawyer as the agent for process, required Plaintiffs to file "this second identical action. . . . as a protective measure within the aforementioned 45-day statutory period, to be served later . . . but only in the unexpected event that the Maryland court were to hold that it could not exercise jurisdiction over [Lupin Ltd., which is located in India.]" Pl.'s Motion for Stay at 4 (Document No. 4).

While Plaintiffs strongly urge Defendants' letter necessitated a "protective suit," however, they do not explain why or if the statutory framework requires such a "protective measure." They point to no case or regulation indicating that "protective actions" are necessary or encouraged in ANDA cases. They do not maintain that "protective actions" "expedite the action" as the statute commands. See 21 U.S.C. § 355(c)(3)(C). They provide nothing to convince this Court they could not pursue this action in solely in Maryland instead of also filing an identical action in this District. According to Plaintiffs,"the basis for personal jurisdiction over defendant Lupin India in Maryland

is particularly strong," yet a "protective suit" is necessary in the event the Maryland court determines it lacks jurisdiction over Lupin Ltd., the India company. Pl.'s Mot. for Stay at 9. This Court cannot accept such a contradictory argument. If the Maryland forum is in any way questionable in order to necessitate a "protective filing" as Plaintiffs maintain, then this Court is clearly the better forum, as all of the parties agree that both jurisdiction and venue lie here. Plaintiffs have therefore failed to justify the need for a stay by "clear and convincing circumstances," as required by Williford, 715 F.2d at 127.

2. Plaintiffs' Additional Arguments

Plaintiffs also maintain this Court should stay the proceedings as a matter of comity. In addition, they assert that Plaintiffs' "blatant forum-shopping should not be countenanced" and this Court should stay the matter to avoid duplicative litigation and inconsistency. These arguments are also unpersuasive.

As the Court has iterated, its primary concern is to "expedite the action" as directed by 21 U.S.C. § 355(c)(3)(C). After hearing from the parties on November 28, 2005 about the progress of the Maryland action, it is evident the Maryland court has proceeded no further in this matter than this Court has. No dispositive rulings have been made. No hearings scheduled. Indeed, a scheduling order has not yet been issued in that suit pursuant to Fed. R. Civ. P. 16(b).[6][7] Generally, although not always, the doctrine of comity involves mutual respect for different sovereigns, commonly

[6]Fed. R. Civ. P. 16(b) requires that a scheduling order "shall issue as soon as practicable but in any event within 90 days after the appearance of a defendant and within 120 days after the complaint has been served on the defendant."

[7]At the November 28, 2005 hearing, this Court set June 6, 2006 as the a trial date in this case. This Court entered a Scheduling Order on November 29, 2005.

between state and federal courts. When two federal courts are involved, the doctrine may also be applied when one court has already rendered a decision. See e.g., Ulmet v. United States, 888 F.2d 1028, 1031 (4th Cir. 1989). In this case, the principle of comity is difficult to apply, as nothing has happened in the Maryland case. The statute requires this action be expedited. The Court is not about to frustrate the statute's purposes for reasons of comity under these circumstances.

As for Plaintiffs' concern about duplicative litigation and inconsistent rulings, the Court observes this problem is easily remedied. Pursuant to Fed. R. Civ. P. 41(1), a voluntary dismissal may be filed by stipulation of the parties. Given that Defendants contest jurisdiction in Maryland, the Court is inclined to believe they will readily enter into such a stipulation with Plaintiffs in order to avoid unnecessary duplicative litigation and inconsistent rulings. Moreover, if duplicative litigation and inconsistency are Plaintiffs' genuine concern, they can only blame themselves. Defendants have been savvy, clearly, but to accuse them of forum shopping strains credulity. Plaintiffs, and no one else, filed two identical lawsuits in two different forums. Plaintiffs, and no one else, alleged jurisdiction and venue in this Court in their Complaint. They should not be surprised this lawsuit is proceeding, as that is what happens when you file suit in this District. This Court is of the firm belief that justice delayed is justice denied. Accordingly, as § 355(c)(3)(C) directs that ANDA actions be expedited and Plaintiffs have not justified the need for a stay by clear and convincing circumstances, their motion to temporarily stay these proceedings is **DENIED.** See Williford, 715 F.2d at 127.

III. Defendants' Motion to Dismiss

A. Standard of Review

Federal Rule of Civil Procedure 12(b)(6) permits a party to move the court to dismiss an action if the plaintiff fails to state a claim upon which relief can be granted. The function of a motion to dismiss for failure to state a claim is to test the legal sufficiency of the complaint. Neitzke v. Williams, 490 U.S. 319, 326-27, 109 S.Ct. 1827, 104 L.Ed.2d 338 (1989). A motion to dismiss should only be granted in "very limited circumstances." Rogers v. Jefferson-Pilot Life Ins. Co., 883 F.2d 324, 325 (4th Cir. 1989). When reviewing the legal sufficiency of a complaint, the Court must construe the factual allegations "in the light most favorable to plaintiff." Schatz v. Rosenberg, 943 F.2d 485, 489 (4th Cir. 1991).

B. Analysis

In its Motion to Dismiss, Defendant Lupin Pharmaceuticals asks this Court to 1) dismiss Lupin Pharmaceuticals as party from this suit, and 2) to dismiss Count 2, the inducement of infringement claim. The Court will address these requests in turn.

1. Lupin Pharmaceuticals as a Party to this Suit

a) Filing the ANDA

Defendant Lupin Pharmaceuticals, the United States subsidiary of Lupin Ltd., first contends it should be dismissed from this suit because Lupin Ltd.'s filing of the ANDA is the only infringing act in this case. In Defendants' view, by § 271(e)(2)(1)'s "plain terms, only the party that submits the ANDA and applies for approval commits an act of infringement." Def.'s Reply Br. in Supp. of its Mot. to Dismiss at 3 (Document No. 20). Plaintiffs argue, however, that because Lupin Pharmaceuticals acted as Lupin Ltd.'s agent when filing the application, Lupin Pharmaceuticals is also liable for infringement. This precise question – whether an agent that is a wholly owned

subsidiary corporation that files and countersigns an ANDA application on behalf of its foreign parent company may also be liable for infringement – appears to be a case of first impression.

Under the Hatch-Waxman Act,

> [i]t shall be an act of infringement to submit . . . an [ANDA application to the FDA] . . . if the purpose of submission is to obtain approval under such Act to engage in the commercial manufacture, use, or sale of a drug or veterinary biological product claimed in a patent or the use of which is claimed in a patent before the expiration of such patent.

35 U.S.C. § 271(e)(2)(1). While the statute, by its terms, does not limit "submit" to the ANDA applicant alone, Defendant Lupin Pharmaceuticals relies very heavily on two cases to support its argument that the statutory term "submit" refers only and always to the ANDA applicant itself. Those cases, however, involve facts distinguishable from the facts before the Court here.

In Geneva, 287 F. Supp. 2d at 584, the district court held that an action for infringement "can only be stated against the party that submits the ANDA." In that case, Geneva Pharmaceuticals ("Geneva") and Zenith Goldline Pharmaceuticals ("Zenith") submitted ANDA applications containing paragraph IV certification stating that SmithKline's patent for Paxil was invalid or would not be infringed by its generic manufacture. Id. at 578. SmithKline then sought leave to amend its complaint to add Sumika Fine Chemicals Co., Inc. ("Sumika") as a defendant, asserting that the ANDAs at issue identified Sumika as a manufacturer of the ingredient used in Paxil tablets. Id. at 579. Adopting the reasoning of SmithKline Beecham Corp. v. Pentech Pharm., Inc., 2001 WL 184804 (N.D. Ill. 2001), a case on which Defendant Lupin Pharmaceuticals also relies, the Geneva court agreed with the Pentech court's conclusion that, because there "is no reference in section 271(e)(2)(A) to suppliers of ingredients of generic drug products or preparers of [a manufacturer's

Drug Master File] relied on by ANDA filers," the provision "refers only to persons who submit ANDAs." Id. at 585 (quoting Pentech, 2001 WL 184804 at *2). Accordingly, both courts rejected SmithKline's contention that the manufacturers should be joined because there was no "authority to support the proposition that a third party can be liable as a direct infringer under Section 271(e)(2) based [on] its 'participation' in another party's filing of an ANDA." Id. (emphasis added).

The case before the Court here, however, is much different. Unlike Geneva and Pentech, this is not a case where a third-party manufacturer uninvolved in the submission of the ANDA is included as party; rather, this case involves a subsidiary of the applicant and that subsidiary submitted the ANDA application to the FDA as agent on the foreign company's behalf. See 21 CFR § 314.50(a)(5). Perhaps it takes a businessman as opposed to a lawyer to discern that a subsidiary is much different from a third-party manufacturer. While it is of course the case that a parent company is not liable for the actions of its subsidiary solely because of the parent-subsidiary relationship, that doesn't mean, as Defendant Lupin Pharmaceuticals seems to suggest, no relationship exists at all. Many foreign corporations utilize United States subsidiaries for tax purposes as well as to market, manufacture, and distribute their products. Indeed, Lupin Pharmaceuticals' own website indicates it does much more than submit ANDA filings on behalf of its parent as it suggests. In a section titled "Who Are We?," Lupin Pharmaceuticals' site states:

> A wholly owned subsidiary of Lupin Limited, Lupin Pharmaceuticals, Inc. is committed to bring specialty products, generic products, and API manufactured by Lupin to the US market.

Pl.'s Motion to Stay at Ex. 3; see also www.lupinworld.com/lupininc/about-us_who.html (last visited Dec. 1, 2005). In a section title "Our Mission," Lupin Pharmaceuticals similarly proclaims

its relationship to Lupin Ltd.

> In pursuit of our mission, Lupin Pharmaceuticals intends to bring a wide portfolio of generic as well as branded products to market.

Id.; see also www.lupinworld.com/lupininc/about-us_mission.html (last visited Dec. 1, 2005). Accordingly, Defendant Lupin Pharmaceuticals' attempt to compare its role to "Washington-based consulting group[s]" where "[a]ll they do is serve as the FDA agent for Indian based companies, Chinese based companies in which they file these or submit the ANDAs on behalf of these companies" is not persuasive given Lupin Pharmaceuticals' own representations on its own website. See Tr. of Nov. 29, 2005 Hearing at 35.

In addition, Lupin Pharmaceuticals is more than a subsidiary of the ANDA applicant in this case. It served as an agent on its parent company's behalf and countersigned the ANDA application. As noted supra, 21 CFR § 314.50(a)(5) requires "[i]f the person signing the application does not reside or have a place of business within the United States, the application is required to contain the name and address of, and be countersigned by, an attorney, agent, or other authorized official who resides or maintains a place of business within the United States."[8] Section 314.3, the definitions section, does not define the term "agent" or "countersigned." The Second Restatement defines agency as follows.

> (1) Agency is the fiduciary relation which results from the manifestation of consent by one person to another that the other shall act on his behalf and subject to his control, and consent by the other so to act.
>
> (2) The one for whom action is to be taken is the principal.

[8]Discuss service of process provision.

(3) The one who is to act is the agent.

RESTATEMENT (SECOND) OF AGENCY § 1(1958). Black's Law Dictionary, meanwhile, defines "countersign" as "[t]o write one's own name next to someone else's to verify the other signer's identity." BLACK'S LAW DICTIONARY 7th Ed. 354. Accordingly, unless the regulation indicated otherwise, this Court does not think serving as agent who verifies the applicant's identity before the FDA is a meaningless role. Defendant Lupin Pharmaceuticals has certainly provided no support for its assertion that a United States agent filing on behalf of a foreign company is nothing more than a "mailbox."

The Court is not convinced at this time that it should dismiss Lupin Pharmaceuticals as a party from this lawsuit. The Court is mindful that the ultimate purpose of this litigation is to determine whether Plaintiff Aventis' '722 patent has been infringed. Under the Act, patent infringement is defined as follows:

> . . . . whoever without authority makes, uses, offers to sell, or sells any patented invention, within the United States or imports into the United States any patented invention during the term of the patent therefor, infringes the patent.

35 U.S.C. § 271(a) (emphasis added). Lupin Pharmaceuticals' own website discusses its business as marketing generic drugs in this country. Plaintiffs' Amended Complaint clearly alleges that both Lupin Ltd. and Lupin Pharmaceuticals infringed the "'722 patent by making, using, offering to sell, importing, and selling Lupin's Ramipril Capsules in the United States." Pl.'s Amend. Comp. ¶ 21 (Document No. 4) (emphasis added). Given that the Court must construe the factual allegations "in the light most favorable to plaintiff" when deciding a motion to dismiss and reviewing the legal

sufficiency of a complaint, Schatz, 943 F.2d at 489, the Court is not inclined to dismiss a subsidiary that filed and countersigned an ANDA application on its parent's behalf under these circumstances where it appears to be the parent's marketing arm in the United States.

b) Sufficiency of the Allegations

Lupin Pharmaceuticals also contends Plaintiffs' "conclusory allegations are insufficient as a matter of law" to state a claim for infringement against Lupin Pharmaceuticals, specifically maintaining that "Plaintiffs must allege facts sufficient to warrant disregarding the separate corporate formalities of a parent and subsidiary." Def.'s Mem. in Supp. of Mot. to Dismiss at 9 (Document No. 9). Plaintiffs, on the other hand, contest Defendants' contention that their Amended Complaint is legally insufficient, noting that Defendants' disagreement with the facts is not a grounds for dismissal.

Under Fed. R. Civ. P. 8, all that is required in a complaint is "a short and plain statement of the claim showing that the pleader is entitled to relief." The Federal Circuit, notably, has emphasized that the "notice pleading" standard applies in the patent context to avoid "needless steps to the already complex process of patent litigation." Phonometrics, Inc. v. Hospitality Franchise Sys., Inc., 203 F.3d 790, 794 (Fed. Cir. 2000). Accordingly, "a patentee need only plead facts sufficient to place the alleged infringer on notice. This requirement ensures that an accused infringer has sufficient knowledge of the facts alleged to enable it to answer the complaint and defend itself." Id.

The Court **FINDS** that Plaintiffs has sufficiently stated a claim of infringement against Lupin Pharmaceuticals. Plaintiffs begin their Amended Complaint by stating they refer to Lupin Ltd. and

Lupin Pharmaceuticals "collectively" throughout the complaint. Pl.'s Amend. Comp. at 1 (Document No. 4). They go on to allege, in Count 1 of the complaint, that "Lupin's" submission of the ANDA constitutes infringement and, "[u]nless enjoined by this Court, Lupin, upon FDA approval of Lupin's ANDA, will infringe the '722 patent by making, using, offering to sell, importing, and selling Lupin's Ramipril Capsules in the United States." Id. ¶¶ 20, 21. This is clearly enough to put Defendants on notice they must answer the complaint and defend themselves against a patent infringement claim. Defendants are well aware that, upon submitting their ANDA application having "paragraph IV certification" and sending a "notification letter" to Plaintiffs, Plaintiffs must bring such a claim within 45 days under the statute or the ANDA application would be approved. See 21 U.S.C. § 355(c)(3)(C). Consequently, Defendants Lupin Pharmaceuticals' contention that Plaintiffs have not sufficiently alleged a patent infringement claim against it is without merit.

2. The Inducement of Infringement Claim

Defendant Lupin Pharmaceuticals also asks this Court to dismiss Count 2, Plaintiffs' inducing of infringement claim. According to Lupin Pharmaceuticals, an inducing infringement claim may not be based "solely on actions leading up to the filing of an ANDA" and ask this Court to dismiss this claim as a matter of law. Def.'s Mem. in Supp. of Mot. to Dismiss at 7 (Document No. 9). With respect to Defendants' contention that the inducing infringement claim should be dismissed, Plaintiffs note their claim is based on Lupin Pharmaceuticals' aiding and abetting of Lupin Ltd.'s ANDA filing as well as Lupin Pharmaceuticals' "willful and deliberate inducement of [Lupin Ltd.'s] making, using and selling of a generic version of King's Altace® product in the U.S. upon Defendants' anticipated FDA approval of the ANDA." Pl.'s Mem. in Opp. to Def.'s Mot. to

Dismiss at 7 (Document No. 14). In Plaintiffs' view, these allegations support a claim for inducing of infringement.

In ANDA litigation, an action for induced infringement may be brought pursuant to Section 271(e)(2). Allergan, Inc. v. Alcon Lab., Inc., 324 F.3d 1322, 1331 (Fed. Cir. 2003). Under Section 271(b), [w]hoever actively induces infringement of a patent shall be liable as an infringer." See 35 U.S.C. § 271(b). In order to be liable for inducement, the inducing party must knowingly act and specifically intend to aid the infringement. Geneva, 287 F. Supp. 2d at 585. While "active inducement" requires "an affirmative act of some kind," see id., the majority of courts have held that allegations of activities done in the preparation of an ANDA application are not enough; rather, the claim must include aiding and abetting infringement so that the primary question of the suit may be resolved, namely: "whether, if a particular drug were put on the market, it would infringe the relevant patent." Pfizer, Inc. v. Ranbaxy Lab. Ltd., 321 F. Supp. 2d 612, 616 (D. Del. 2004).

The Court **FINDS** Plaintiffs have sufficiently alleged a inducing infringement claim against Lupin Pharmaceuticals. In the Amended Complaint, Plaintiffs allege inducing infringement against Lupin Pharmaceuticals in Count 2. Pl.'s Amend. Compl. ¶ 28. They then "reallege paragraphs 1 through 26 as if fully set forth herein." Paragraph 7 states: "On information and belief, that acts of Lupin Ltd. complained of herein were done at the direction of, with the authorization of, and/or with the cooperation, participation, and assistance of, and at least in part for the benefit of, Lupin Pharmaceuticals, Inc." Id. ¶ 7. While the filing of the ANDA application spurred Plaintiffs' complaint and created subject matter jurisdiction for it, as noted supra, the ultimate question in this case is patent infringement, as alleged in Count 1: whether the '722 patent will be infringed by the "making, using, offering to sell, importing, and selling Lupin's Ramipril Capsules in the United

States." Plaintiffs' complaint therefore consists of more than a complaint about an ANDA filing as Defendants contend. Thus the Court **DENIES** Plaintiffs' motion to dismiss the inducing infringement claim.

IV. Conclusion

The Court is not surprised to see both sides in this case attempt what they have attempted here. Plaintiffs have much to gain by delaying any generic competition to their pioneer drug, ramipril. Thus they have strenuously argued for a temporary stay in this case. Plaintiffs, however, were not able to convince this Court that a stay was merited. The statute requires the parties expedite this action. A stay would run counter to that statutory command. Plaintiffs' Motion to Temporarily Stay Proceedings is **DENIED.**

Lupin Pharmaceuticals similarly had much to gain if it had succeeded on its Motion to Dismiss. Arguably, if Lupin Pharmaceuticals had been dismissed from this case, the remedies available under the statute against infringers in ANDA cases would not have applied to it.[9] As the Court explained above, however, Lupin Pharmaceuticals did not overcome the very high threshold utilized in dismissal motions to convince this Court that Plaintiffs' complaint is legally insufficient. Indeed, it appears at this juncture Lupin Pharmaceuticals is much more than an organization that files ANDA applications on its foreign parent company's behalf. If Lupin Pharmaceuticals is possibly

[9]This is what is known as a "heads I win, tails you lose" situation. If Lupin Ltd. prevails in this suit, the dismissal of its subsidiary is of no consequence – marketing the drug may proceed with no problem. If Lupin Ltd. loses this suit, the dismissal of its subsidiary allows that subsidiary to proceed anew. Consequently, if Lupin Pharmaceuticals was dismissed, the only way Lupin Ltd. could lose would be if the coin stopped on its end.

a marketing arm of Lupin Ltd.'s generic version of ramipril, then it is also possibly an infringer. Lupin Pharmaceuticals should therefore remain in this case so that the ensuing litigation will serve its purpose and reveal whether Plaintiffs' '722 patent was infringed or not. Defendants' Motion to Dismiss is **DENIED.**

The Clerk is **DIRECTED** to mail a copy of this Memorandum Opinion and Order to all counsel of record.

IT IS SO ORDERED.

_____ /s/_____
ROBERT G. DOUMAR
UNITED STATES DISTRICT JUDGE

Norfolk, Virginia
December 2, 2005